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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,832	08/10/2001	Albert Gyorkos	2635A/121	7064

2101 7590 11/22/2006

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,832

Applicant(s)

GYORKOS ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,15,16,20 and 30 is/are rejected.
- 7) ☒ Claim(s) 2-14,17-19 and 21-29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20011207</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. The Sequence Listing filed June 16, 2003 is approved.
2. The substitute specification filed August 10, 2001 has not been entered because a clean copy of the substitute specification either was not provided or was not scanned into the image file wrapper. The proposed amendments set forth in the marked-up copy of the substitute specification are acceptable and do not raise issues of new matter.

Applicants are required to submit a clean copy of the substitute specification filed on August 10, 2001 (including the amended abstract, but not including any drawings or claims). The clean copy should include as the first paragraph the most recent claim for priority, i.e. the claim for priority which refers only to U.S. Serial No. 08/985,298 and not to U.S. Serial Nos. 08/760,916 and 08/345,820. The clean copy should be accompanied by a statement that it contains all of the changes included in the substitute specification filed on August 10, 2001. Assuming that no other changes are to be made in the substitute specification, Applicants should not re-submit a marked-up copy of the substitute specification.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
4. Claims 1, 15, and 16 are objected to because of the following informalities: Claim 1, at lines 12 and 13, recites that V_1 and V_2 can each be C; however, this would imply a trivalent carbon atom. It is believed that for these two variables, "C" should instead be "CH". At claim 1, page 116, lines 21-22, the beginning and end brackets and parentheses in "(2-[5-tert-butyl-1,3,4-oxadiazolyl]carbonyl)" do not match. This same error occurs at claim 15, lines 3-4, and at claim 16. Appropriate correction is required.

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 15, 16, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,656,911. Although the conflicting claims are not identical, they are not patentably distinct from each other. The compounds of the instant claims are encompassed within the scope of claim 1 of the '911 patent. In particular, the compound of instant claim 16 differs from the second compound of claim 17 of the '911 patent in that the latter has a butyl rather than a t-butyl group for the variable R₁. It would have been obvious to one of ordinary skill in the art to form a compound in which a t-butyl group is substituted for the butyl group in the second compound of claim 17 of the '911 patent because claim 15 of the '911 patent, upon which claim 17 depends, shows that t-butyl and butyl are interchangeable groups at this position, because the resulting compound is embraced within the scope of claim 1 of the '911 patent, and because the resulting compound has only the serine protease inhibitory activity which would have been expected in view of the '911 patent.

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Also, the compound of instant claim 30 differs from the first compound of claim 13 in that the latter has an (R) rather than an (S) configuration. It would have been obvious to one of ordinary skill in the art to form a compound which has an (S) rather than an (R) configuration in the first compound of claim 13 of the '911 patent because the resulting compound is embraced within the scope of claim 1 of the '911 patent, because the resulting compound has only the serine protease inhibitory activity which would have been expected in view of the '911 patent, and because the similarity in chemical structure of position isomers provides motivation to make the claimed compound in the expectation that compounds similar in structure will have similar properties. See MPEP 2144.09.

7. Claims 1, 15, 20, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,001,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '814 patent anticipate the instant claims. In particular, the racemic mixture of claim 7 of the '814 patent anticipates the compound of instant claim 20, which is not required to be isomerically pure. The racemic mixture of claim 11 of the '814 patent anticipates the compound of instant claim 30, which is not required to be isomerically pure.

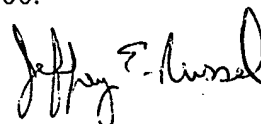
8. Claims 2-14, 17-19, and 21-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The three U.S. patent applications cited on the Information Disclosure Statement filed December 7, 2001 have been crossed out so that they can be cited separately and more completely on the attached PTO-892, Notice of References Cited.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

November 16, 2006